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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,622	12/21/2000	Curtis Cole	JBP-534	7817

7590 10/21/2003

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EXAMINER

YU, GINA C

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/21/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/742,622

Applicant(s)

COLE ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20, 21.
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 25, 2003 has been entered. Claims 1-23 are pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that an acid salt is formed from an amino alkyl alcohol and "a mixture of anionic counterions derived from at least two pharmaceutically acceptable acids and esters thereof". According to the formula of the acid salt shown in applicants' specification, the salt contains only one anionic counterion. The claim is vague and indefinite because the acid salt as claimed cannot be formed as recited, according to the applicants' disclosure.

The remaining claims are rejected as depending on an indefinite base claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (US 4197316). (“Yu”).

Yu discloses a method to treat dry skin, including facial skin, using topical composition which comprise one or more alpha hydroxy acids, esters thereof, and their ammonium salts. See abstract; col. 1, lines 16 – 40. See instant claims 13 and 14. Compositions containing ethanolamine salt of glycolic acid, and triethanolamine salt of lactic acid are disclosed. See Examples 1-5. The reference teaches that secondary amines such as N-methylethanolamine and N-ethylethanolamine. See col. 3, lines 14 – 25. A solution containing 2 grams of glycolic acid, 2 grams of citric acid, and ethanolamine is disclosed in Example 5. See instant claim 17. Using malice acid is also suggested. See col. 1, line 60; col. 3, line 30. The Yu reference also teaches that N-ethylethanolamine is a suitable secondary amine for the invention.

Examiner takes the position that the claimed method of improving “the appearance of facial contours” is met because the prior art method is to improve a skin condition.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-11 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 13-17 as above, and further in view of Znaiden et al. (US 5523090) ("Znaiden") and Perricone (US 5554647).

As discussed above, the recited acid salt of alkaloamine is known in the dermatological art. The pH of the solutions of the examples range from 4.4 to 4.7, while the reference generally teaches that the pH of the final composition may range from 3.5-7.5. See instant claims 9 and 20. While the Yu reference fails to expressly teach that the claimed methods of improving "the firmness of skin", and "reducing the appearance of sagging skin", examiner notes that these improvements are associated with treating aging skin. While Yu teaches that malic acid may be used, the reference fails to teach the specific weight ratio of the malic acid and glycolic acid.

Znaiden discloses skin treatment compositions for improving skin strength and firmness, which comprise salts of alpha hydroxy acids and caffeine. The reference teaches that it is well known in the art that alpha hydroxy acids improve "the appearance dry, flaky, wrinkled, aged, photodamaged skin". See col. 2, lines 13 – 20. While a composition containing 1:1 weight ratio of malic acid and lactic acid is disclosed in example 12, the reference fails to teach the specific example of combining malic acid and glycolic acid. The reference, however, teaches that the most preferred acids in the invention include glycolic acid and lactic, and the reference further teaches that the choice of these alpha hydroxy acid depends on the efficacy of compositions in increasing percutaneous absorption. See col. 5, lines 43 – 45. See instant claim 18.

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In general, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Yu and Znaiden, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation. See instant claim 19.

Perricone teaches that topical application of acetylcholine precursors such as dimethylaminoethanol in a dermatologically acceptable carrier is effective in shortening of muscles, producing increased tone, enhancing the appearance of the skin, and results in a smoother, tighter, and more youthful appearance for aging persons and patients afflicted with conditions that cause sagging faces". See abstract; col. 3, line 36 – col. 4, line 5; col. 8, lines 10-29. See instant claims 10 and 21.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Yu composition by applying the composition to treat dry, flaky, wrinkled, aged, and/or sagging skin as motivated by Znaiden and Perricone, because of an expectation of successfully producing toned, smoother, tighter, and more youthful appearance on the skin. Examiner takes the position that the motivation and the expectation of success is found in the collective teachings of the references that the recited alkaloamines and the alpha hydroxy acids are each well known in treating aged skin conditions.

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2. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, Znaiden, and Perricone as applied to claims 1-11 and 13-23 above, and further in view of Quan et al (U.S. Pat. No. 6,180,133 B1) ("Quan").

The combined references fail to teach using the composition with the articles as required by claim 12.

Quan teaches an adhesive, matrix-patch for treating wrinkle. The adhesive contains mixture of vitamins, alpha hydroxy acids or their salts, and glycerine. See col. 3, line 45 – col. 4, line 63; col. 4, lines 44 – col. 5, line 23. The reference teaches that the administration of the composition with the patch system is more effective than by hand, and provides the enhanced absorption of the therapeutic components into the skin. See col. 7, lines 7 – 35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the Yu reference by incorporating the compositions into an adhesive patch, as motivated by Quan, because of expectation to have successfully administered the therapeutic components in the combined references more effectively.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-7, 10-12, and 14-16 of copending Application No. 09/677,737. Although the conflicting claims are not identical, both claims are directed to method of using a composition comprising the acid salts of akanolamines having overlapping limitations. The application no. 09/677,737 claims method of ameliorating redness or inflammation of skin, and thus meets the presently claimed method of improving the appearance of facial contour.

This is a provisional obviousness-type double patenting rejection.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of new ground(s) of rejection.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

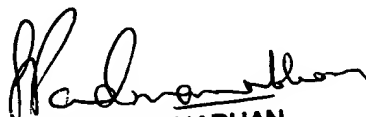


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308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
October 16, 2003

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER

09/20/03